Cover page

Promoting Risk Reduction Among Young Adults with Asthma during Wildfire Smoke Events

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4 Protocol synopsis

4.1 Brief summary

The purpose of this study is to assess the feasibility of a smart phone application (app)-based intervention to reduce risks from wildfire smoke among young adults with asthma. We will pilot test two interventions, both based on the EPA's Smoke Sense phone app compared to a control group. We will recruit 60 young adults aged 18-26 with asthma and randomize them to 1 of 3 groups for a 3-month study period during wildfire season. The long-term goal is to minimize asthma exacerbations from exposure to wildfire smoke. Our aims are to:

1. Establish the feasibility (recruitment, enrollment, retention rates), acceptability (intervention engagement, fidelity, usability, research attitude), and barriers and facilitators of adopting the technology of the Smoke Sense interventions and use of portable devices in young adults with asthma.

2. Explore the preliminary impact of the Smoke Sense interventions on lung function and asthma control. These primary outcomes will be assessed using objective measures (spirometry) and validated, self-report tools. Secondary outcomes will be anxiety, exposure reduction behaviors (e.g. stayed indoors, wore a mask), and symptom mitigating behaviors (use of medication, unscheduled health care appointments), measured via self-report and a Global Positioning System device. Outcome by group will be summarized. Preliminary evidence of treatment effect and its variance will be examined for a future clinical trial.

3. Explore potential mediators (medication adherence, self-management skills, stress) and moderators (asthma severity/control) of the interventions to asthma outcomes.

4.2 Study design

4.2.a. Narrative study description (of the protocol)

We propose an 8 week, 3-arm randomized clinical trial to pilot test two interventions, Smoke Sense and Smoke Sense Plus, in comparison to a control group among young adults with asthma. This research design enables an examination of feasibility and acceptability of processes that are key to the success of a future trial. The design also enables us to estimate the effect size of the Smoke Sense interventions on primary (lung function, asthma control, asthma quality of life) and secondary outcomes of interest (anxiety, exposure reduction behaviors, and symptom mitigating behaviors), as compared to a control group, among young adults with asthma. Measures will be assessed at baseline, 4 and 8 weeks. The intervention period is 8 weeks. The sample will consist of 60 young adults, 18-26, with diagnosed asthma (of any type). Study activities will take place during wildfire season, July-October. To be included in the study, participants will need to have been diagnosed by a health care provider as having asthma, own a smart phone (Android or iOS platforms), speak and read English, and reside in Spokane County, WA. People can not be in the study of they are a Smoke Sense app user, have had surgery within 3 weeks of enrollment, or a cardio-vascular condition, both of which are contraindications for spirometry[56].

The choice of sample size (n=60 participants) was based on achieving Aim 1, focusing on assessment of the feasibility and acceptability of the Smoke Sense interventions. *Feasibility.* We expect that the true consent rate of eligible young adults is 75%.[67, 68] To test this, we will recruit up to 86 eligible individuals. There is an 89% probability that 60 or more of these individuals will consent to participate if the true consent rate is 75% (based on the cumulative binomial probability). We expect that the true rate of completion of the week-8 assessment is 80%.[69] If this is correct, there is an 87% probability that we will observe at least 45 out of 60 participants completing the week-8 assessment. Similarly, we expect that the true rate of completion of the week-8 assessment is 75%.[69] If this is correct, there is an 85% probability that we will observe at least 42 out of 60 participants completing the week-8 assessment.

Acceptability. We hypothesize that the true intervention adherence (adoption) rate for the two intervention groups is 70% and 85%, Smoke Sense and Smoke Sense Plus, respectively. If this is correct, there is an 87% probability that we will observe that at least 12 out of 20 participants will adhere to Smoke Sense. There is a 93% probability that we will observe at least 15 out of 20 participants will adhere to or Smoke Sense Plus.

Young adults will be recruited from Washington State University-Spokane, and the Community Colleges of Spokane. (See LOS). Recruitment messages will be posted to social media sites and sent via the respective student affairs offices and health clinics to student list servs. A phone screening will determine study eligibility. If eligible, we will invite participants to the clinical laboratory at WSU Spokane for study visit 1 (Timepoint 1). Research personnel will consent the participant.

Eligible young adults will be randomized with equal probability to 1 of 3 study groups in blocks of 2, 4 and 5. Random assignment of the 60 participants will be determined by Dr. Odom-Maryon using a randomization software. Random group assignment and a corresponding unique study identification (ID) number will be placed in sealed envelopes that are numbered sequentially from 1-60. After the consent is signed, research personnel will open the envelope to reveal the participant's group assignment. Research personnel will record the participant's name, study ID and group assignment in a password protected spreadsheet stored on a secure server at WSU. As part of the training, participants will download the appropriate app to their mobile phones. A set-up macro will ask the participant to enter their study ID which can be associated with all study data captured by the app.

A phone screening will determine study eligibility. If eligible, we will invite participants to the clinical laboratory at WSU Spokane for visit 1 (T1). A research assistant (RA) will consent and randomize the participant but the investigative team will be blinded to group assignment. Participants will fill out a series of questionnaires via a link sent to their phone. The RA will weigh and measure the participant. The RA will train the participant on the use of a portable digital spirometer with a mouthpiece that connects to the participant's smartphone. The participant will download spirometry software onto their phone and enter their age, sex, height and weight. Participants will be asked to practice exhaling into the mouthpiece. This air turns a motor while the device registers the speed, adapts it and transfers the measurement the participants' smartphone application. When a participant initiates exhalation, a chronometer changes from red to green after 6 seconds of exhalation. Users can visualize their exhalation curve via the color change and see if they have made an error. The device will select the best result out of 3 attempts. Participants will be asked to return-demonstrate the process until they have definitive results. No calibration is required. Participants will also receive a GPS device and will be instructed on its continuous use during waking hours. Participants will be told that they will be sent an email with a link to a suite of Qualtrics' surveys, which they will be asked to complete via their phone at T2, T3 and T4. Participants in both intervention groups will be instructed on how to download and use the Smoke Sense app. Participants will be asked to return to the clinical lab so research personnel can download their GPS data at T2, T3 and T4. At T4 they will return their spirometer and GPS unit, and complete the System Usability Scale[60] and the Research Attitudes Questionnaire.[61] They can earn $150, in $50 increments, per visit, T2-T4.

This study proposes 2 intervention groups: Smoke Sense and Smoke Sense Plus. Smoke Sense Plus offers potentially value-added preventive activities to Smoke Sense. We hypothesize that with these additional activities, users will take actions to reduce their exposure before experiencing symptoms and reduce the severity of outcomes.

Upon downloading, the Smoke Sense mobile app prompts users to set up a ***Profile***, which includes a zip code, demographic information (sex, age, race, education level), baseline health information (pre-existing conditions, physical activity level, time spent outdoors), and beliefs about smoke and air pollution (e.g. Does smoke impact health?). In the ***Symptoms & Smoke***

Observations tab, participants report their weekly observations of smoke, health symptoms, and exposure reduction behaviors. Four symptom categories are reported, eyes and ears, respiratory, cardiovascular, and/or other, as well as the severity of adverse health effects (i.e. symptom duration, whether medication was used, and whether an unplanned trip to a health care provider occurred). In the *Fire & Smoke Near Me* tab, participants can look at current AQ data measured at monitoring sites and future forecasts. The *AQ 101* module leads to trivia games which test knowledge of AQ facts and provides correct answers. Badges are awarded for accomplishments to promote desired behaviors: completing a user profile, launching the app weekly to check local AQ, reporting smoke and symptom observations, expanding AQ knowledge with AQ lessons, and exploring the map. Finally, participants can *engage with other users* by viewing cumulative statistics of symptoms and smoke observations.

Participants randomized to Smoke Sense Plus will be asked to engage in the Smoke Sense app, as well as additional, evidence-based activities, including:[18, 19] 1) Receive weekly, push notifications that remind them to, for example, review their asthma action plan, take their daily controller medication, refill any expired medications, and identify places to go with filtered indoor air (e.g. library), 2) Monitor lung function daily using a portable spirometer, and 3) Subscribe to a social network to share spirometry data, and exposure reduction strategies. Both interventions will be delivered via participants' smart phones.

The control group will receive incentives for study participation but will not be introduced to the Smoke Sense app.

4.2.b Purpose: PREVENTION

4.2.c Intervention Type: behavioral

IVN Name: Smoke Sense

Description: Smoke Sense is a smartphone application (app). Smoke Sense participants will be asked to establish a profile which includes demographics, baseline health information and current beliefs about smoke and air pollution. In the Symptoms & Smoke Observations tab, participants are asked to report their weekly observations of smoke, health symptoms, and exposure reduction behaviors. In the Fire & Smoke Near Me tab, participants review the most recent AQ data measured at an AQ monitoring sites. Participants are asked to complete the AQ 101 module which test knowledge of AQ facts and provides correct answers. Badges are awarded for accomplishments within the app to promote certain desired behaviors: completing a user profile, launching the app weekly to check local AQ, reporting smoke and symptom observations, expanding AQ knowledge with AQ lessons, and exploring the map. Finally, participants can engage with other users by viewing cumulative statistics of symptoms and smoke observations.

Intervention Type: behavioral

IVN name: Smoke Sense Plus

Description: Participants randomized to the Smoke Sense Plus intervention will be asked to do everything that the Smoke Sense intervention group does on a weekly basis, as well as the following additional activities: 1) Receive weekly push notifications that remind them to, for example, review their asthma action plan, refill any expired medications, take their daily controller medication, identify a clean air space in their home and community, 2) Monitor their lung function weekly via mobile spirometry, and 3) Subscribe to a social network to share strategies to minimize exposure.

4.2.d. Study phase

N/A or “OTHER” This is a behavioral intervention

4.2.e. IVN study model: Parallel

4.2.f. Masking: Investigator

4.2.g: Randomized

4.3 Outcome measures

Primary: Lung function

Repeated assessment throughout the 8 week intervention and follow up period.

Lung function indicates future risk of adverse outcomes and is regularly monitored in people with asthma[58]. Spirometry is used to objectively measure and monitor airway obstruction by blowing into a machine and measuring forced expiratory volume (FEV1), forced vital capacity (FVC), and their ratio (FEV1/FVC). A low FEV1, <60% predicted, is a potentially modifiable independent risk factor for severe asthma exacerbations. Portable spirometers, that are used by patients independently and connect to smartphones, have been validated against conventional spirometry performed by specialists in clinical settings.[50]

Primary: Asthma Control Test

Repeated assessment throughout the 8 week intervention and follow up period.

The **Asthma Control Test** (ACT)[59] measures the frequency of shortness of breath and general asthma symptoms, use of rescue medications, effect of asthma on daily functioning, and an overall self-assessment of asthma control via self-report. It has 5 items, uses a 4 week recall on symptoms and daily functioning and has a response scale that ranges from 5 (poor control) to 25 (complete control). ACT score >19 indicates well-controlled (versus 19 or < poorly controlled) asthma. The Minimally Important Difference (MID) is 3 points between two groups or for changes over time.[60]

4.4 Statistical Design and Power

Data management. Spirometry and questionnaire (via Qualtrics) data will be captured through apps installed on the participants’ smartphone. GPS data will be downloaded at T2, T3 and T4 from the device. GPS data will be uploaded to the Urbanova cloud where it will be processed, cleansed, and de-identified. All other data will be sent directly to Urbanova for processing, de-identification, and integration.

Analytic plan. Feasibility, acceptability, and study outcomes (both primary and secondary) will be compared among the 3 study groups using descriptive statistics. Categorical and continuous data will be summarized as frequencies (percentages) and means (standard deviations [SDs]), respectively. Graphical displays and confidence intervals (CIs) will also be used to characterize group differences. Pursuant to Aim 1, descriptive statistics will be used to examine recruitment and retention rates, and characteristics of participants (Table 2 measures) who dropout early to those who complete the study. The primary outcomes for Aims 2 and 3 include lung function (FEV1, FVC and FEV1/FVC ratio measured by spirometry), asthma control (ACT), and asthma quality of life (Juniper’s AQLQ score averaging across items by domain and overall). To explore the preliminary impact of the Smoke Sense interventions on these primary outcomes (Aim 2), changes in means (SDs) across study timepoints will be examined for ceiling and floor effects,

restrictions in range and achievement of MID for each outcome. Generalized linear mixed models (GLMMs) will be fit that include main effects for study group and time point (1=baseline, 2=4 weeks, T3=8 weeks) and the interaction. An identity (continuous outcome) or logit (binary outcome) link function will be specified using SAS 9.4[74] PROC GLMMIX. Correlations within-participant over repeated measures of time will be controlled for using a random intercept model and a variance component covariate structure. The interaction terms and the slope coefficients for the 3 study groups will be of central interest to characterize changes in each of the outcomes across time. The same analytic approaches will be applied to the secondary (self-report) outcomes including anxiety, exposure reduction behaviors, and mitigating behaviors. Objective measures of exposure reduction behaviors will be estimated using GPS data. To examine the association between each of the GPS-based behaviors and study group during periods of poor AQ, full factorial GLMMs will be fit that include group, day, AQ (1=poor or worse, 0=normal) and specify a random intercept model with an autoregressive covariance structure.

Analyses will examine if the efficacy of the Smoke Sense interventions on outcomes is mediated (adherence to medication therapy, level of self-management skills, and psychological stress) or moderated (asthma severity/control) (Aim 3). For the mediation analyses, PROC CAUSALMED will be used for bootstrapping the CIs of the indirect effects or p-values for the corresponding tests. For moderation by asthma severity/control, we will run the same set of analyses proposed for Aim 2, now including an additional main effect of asthma severity/control and an interaction term of asthma severity/control by study group. We will graph the means of each outcome across subgroups to better understand what, if any, interaction is present. For Aims 2 and 3, two-sided statistical tests will be performed (alpha=0.05). The results from all of the statistical tests performed in Aims 2 and 3 will be interpreted as hypothesis-generating for a future R01 grant submission.

Missing data. If the assumption of "missing at random" can be safely satisfied, GLMM appropriately uses maximum likelihood methods to handle missing data. If this assumption is not satisfied, sensitivity analyses will be performed to examine the impact of different assumptions (e.g. missing not at random) on intervention effects.[75]

Program Feasibility, Fidelity and Impact. Program feasibility[51] will be determined by whether or not the rates of recruitment, enrollment, retention in the study (outlined in the Sample Size justification, below) are met. Intervention acceptability will be determined by a high level of engagement with, and adherence to, the Smoke Sense and Smoke Sense Plus interventions. Acceptability of the portable devices used in data collection will be measured using the System Usability Scale,[60] and the Research Attitude Scale.[61]

Sample Size Justification. The choice of sample size (n=60) was based on achieving Aim 1, focusing on assessment of the feasibility and acceptability of the Smoke Sense interventions. *Feasibility.* We expect that the true consent rate of eligible young adults is 75%.[76, 77] To test this, we will recruit up to 86 eligible individuals. There is an 89% probability that 60 or more of these individuals will consent to participate if the true consent rate is 75% (based on the cumulative binomial probability). We expect that the true rate of completion of the T3 assessment is 80%.[78] If this is correct, there is an 87% probability that we will observe at least 45 out of 60 participants completing the T3 assessment. Similarly, we expect that the true rate of completion of the T4 assessment is 75%.[78] If this is correct, there is an 85% probability that we will observe at least 42 out of 60 participants completing the T4 assessment. *Acceptability.* We hypothesize that the true intervention adherence rate for the two intervention groups, Smoke Sense and Smoke Sense Plus, is 70% and 85%, respectively. If this is correct, there is an 87% probability that we will observe that at least 12 out of 20 participants will adhere to Smoke Sense. There is a 93% probability that we will observe that at least 15 out of 20 participants will adhere to Smoke Sense Plus.

Potential problems and alternative strategies. Age could be broadened if recruitment is a challenge. If AQ is uncharacteristically healthy during the study period, we will use WSU-

Extension to recruit in areas with poor AQ. Data collection may influence behavior change. To examine this, we will assess matched outcomes among national Smoke Sense users and our control group. While not feasible in this study, we will include a future attention control group. Use of spirometry may decrease the magnitude of the interventions' effect. However, the benefits of measuring lung function objectively outweigh the potential decrease in effect sizes.

WASHINGTON STATE UNIVERSITY
COLLEGE OF NURSING

Research Study Consent Form

Study Title:
Promoting Risk Reduction among Young Adults with Asthma during Wildfire Smoke Events

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Sponsor: National Institute of Nursing Research

Financial Conflict of Interest: The Washington State University Financial Conflict of Interest committee has evaluated the management plan to reduce the possible effects of this relationship on human subject safety and welfare.

External Funding: National Institute of Nursing Research

What you should know:
You are being asked to take part in a research study carried out by Dr. Postma, Dr. Odom-Maryon, Dr. Amiri, Dr. Walden, Dr. Butterfield, Dr. Ana Rappold, Dr. Haverkamp and Dr. Bindler. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain

anything you do not understand. Your participation in the study is voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This is a clinical trial and should not be considered medical treatment. If you experience any medical concerns, please consult with your doctor. In case of emergency, call 911.

This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is the purpose of this study?

This research study is being done to examine the impact of wildfire smoke on young adults with asthma, and to understand how we can use smart phone applications to help prevent people from breathing polluted air. We will monitor your activity, breathing function, and symptoms during the study. You are being asked to take part because you are 18-26 years old, have been diagnosed with asthma by a health care provider, own a smart phone (Android or iOS platforms), and speak and read English. You cannot take part in this study if you do not meet the previously mentioned criteria or if you already use the 'Smoke Sense' phone application, smoke, have had surgery within 3 weeks of study start date, have a cardiovascular condition, or have or have had COVID-19. If a person was negative upon enrollment but tests positive for COVID 19 while enrolled, exclusion is temporary until they test negative.

What will I be asked to do if I am in this study?

If you take part in the study:

- You will be asked to:
    - Participate in the study for two months.
    - Participate in a virtual study visit to learn about the study. During that visit you will learn how to use a hand-held digital spirometer and download its software application (app) to your smart phone. We will also ask you to download a Global Positioning System (GPS) app and fill out a series of questionnaires on your phone.
    - Two, four and eight weeks after your virtual study visit, you will be asked again to fill out a series of questionnaires on your phone and use your hand-held digital spirometer. One example of a question that we will ask you is, "During the past 4 weeks, how often have you had shortness of breath?"
- Taking part in the study will take between 3 and 10 hours of your time, depending on the study group you are randomly assigned to. Random assignment is like flipping a coin to determine what study group you will be assigned to.

- If you are assigned to the 'Smoke Sense' intervention group, you will also be instructed on how to download and use the Smoke Sense app. You will be asked to use the app weekly for two months, which we call the "intervention period."
- If you are assigned to the to 'Smoke Sense Plus' intervention group, you will also be asked to use the Smoke Sense app weekly for two months, as well as:
  1) Use your spirometer everyday,
  2) Receive weekly reminders to, for example, review your asthma action plan, and,
  3) Participate in a social network with other people in your study group to share ways that you stay healthy during wildfire smoke.

- About 60 people will participate in this study.

Are there any benefits to me if I am in this study?
There are no direct benefits to you for taking part in this study. Your participation will help us learn how to prevent asthma attacks in other people.

Are there any risks to me if I am in this study?
The potential risks of being involved in this study are invasion of privacy and breach of confidentiality. Strategies are in place to protect you from these risks. You will be given a study ID. Each spirometer will be assigned a unique study ID. Through this approach, no identifiable data will be sent to the cloud about you. We will use automated scripts to process your location data from the GPS app. Data processing will tell us the number of minutes you stayed indoors, outdoors, or in a vehicle daily without exploring where you live, work or study. If privacy is violated or confidentiality is breached, we will inform you, revisit our protocol for data management and update it to ensure we prevent another breach. We will alert the IRB at WSU as well as the Vice Chancellor for Research on the Spokane campus.

Will my information be kept private?
The data for this study will be kept confidential to the extent allowed by federal and state law. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project. We will assign you a study code to link your questionnaires, spirometer results, and activity information from your GPS and Smoke Sense apps. There will be one file that will have both your name, home and work or school address, and your study code. That file will be password-protected and stored on the secure, WSU shared drive to keep your information private. In addition, data from the spirometry, GPS, and questionnaires will be coded when we collect that information.

Coded (de-identified) data will be stored on the Urbanova Cloud which protects data from unauthorized access and from data loss by using data encryption, identity and access controls,

data retention policies and data version control. Your information can only be accessed by a member of the research team or Jon Thompson, Chief Technologist at Urbanova. The Urbanova Cloud supports identity and access management standards. Members of the research team will have access to the study data on the Urbanova Cloud. They will use multi-factor authentication to access study information. Members of the WSU Human Research Protection Program, the WSU Institutional Review Board, and or the WSU data custodian may also access the data for regulatory purposes. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

The data for this study will be kept for 3 years. At that point, any identifiable information will be destroyed. De-identified information may be used for future research studies.

Are there any costs or payments for being in this study?
There will be no costs to you for taking part in this study. You can earn between $100 and $200 in Amazon gift cards depending on your group assignment. The gift cards will be emailed after each data collection point. If you decide to quit the study, you will not receive any gift cards beyond the point in the study when you quit. For example, if you quit the study after the third data collection point, you would not have to return the gift cards you earned at the second or third data collection point, but you would not earn any additional gift cards.

Who can I talk to if I have questions?
If you have questions about this study or the information in this form, please contact Dr. Julie Postma, PhD, Principal Investigator (lead), Associate Dean for Research, Associate Professor, Washington State University, College of Nursing, 509-324-7287, jpostma@wsu.edu, 412 E. Spokane Falls Blvd, Spokane, WA 99202-2131. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: Neill 427, PO Box 643143, Pullman, WA 99164-3143.

In order to withdraw your previously collected data from the study you must contact Dr. Julie Postma, PhD, Principal Investigator (lead), Associate Dean for Research, Associate Professor, Washington State University, College of Nursing, 509-324-7287, jpostma@wsu.edu, 412 E. Spokane Falls Blvd, Spokane, WA 99202-2131. There are no consequences for withdrawing from the study.

What are my rights as a research study volunteer?
Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may

choose not to answer specific questions or to stop participating at any time. You will be given a copy of the consent form for your records.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- You are giving your voluntary consent to take part in the study.

Statement of Consent

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

Are you willing to be contacted later about future studies about asthma?

- o YES, I agree to be contacted for future asthma studies.
- o NO, I do not agree to be contacted about future asthma studies.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent